



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

**SUPPLEMENTARY INFORMATION:** Technology description follows.

## **Zika Virus Vaccines**

### **Description of Technology:**

Zika virus (ZIKV) is a flavivirus transmitted by mosquitos that is strongly linked to neurological complications including Guillain-Barré syndrome, meningoencephalitis, and microcephaly. The association between active ZIKV infection during pregnancy and microcephaly and intrauterine growth retardation in the fetus has been confirmed in murine models of ZIKV infection.

Scientists at NIAID have developed nucleic acid-based vaccine candidates to prevent ZIKV infection in humans. The current lead candidate vaccine is a plasmid DNA vaccine demonstrated to accord protection in preclinical models and is undergoing clinical trial evaluation. Nucleic acid-based vaccines have been developed previously for West Nile virus, another flavivirus similar to Zika (J.E. Ledgerwood, et al. J. Infect. Dis. (2011) **203** (10): 1396-1404). Immunization with the nucleic acid ZIKV vaccine candidate results in production of noninfectious virus like particles (VLPs) made of ZIKV proteins. These ZIKV VLPs elicit an immune response which includes neutralizing antibodies to ZIKV.

Other preclinical ZIKV vaccine candidates include mRNA, protein, and noninfectious VLPs.

NIAID is continuing development of these vaccine candidates. The DNA-based ZIKV vaccine candidate is currently in clinical trials. Consequently, for some fields of

use, NIAID will evaluate a license applicant's capabilities and experience in advancing similar technologies through the regulatory process.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR Part 404, as well as for further development and evaluation under a research collaboration. This technology is not eligible for NIH's start up license.

**Potential Commercial Applications:**

- Prevention of Zika virus infection

**Competitive Advantages:**

- There is currently no licensed Zika virus vaccine

**Development Stage:**

- Currently, DNA-based vaccine candidate in Phase I clinical trial
- Phase II clinical trial planned for early 2017 for DNA-based vaccine candidate
- Other candidates are in pre-clinical development

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**Intellectual Property:** US Patent Application No. 62/396,613 filed September 19, 2016 (HHS Reference No. E-181-2016/0-US-01).

**Licensing Contact:** Dr. Amy Petrik, 240-627-3721; amy.petrik@nih.gov.

**Collaborative Research Opportunity:** The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Zika virus vaccine technologies. For collaboration opportunities, please contact Dr. Amy Petrik, 240-627-3721; amy.petrik@nih.gov.

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